-02-07

Attorney's Docket No.: 21865-002001/6502

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mang et al. Applicant

Art Unit : 1652

Serial No.

10/718,986

Examiner

Tekchand Saidha, Ph.D.

3664

Filed

November 21, 2003

Conf. No.

Title

Cust. No. 20985 : ANTIVIRAL RECOMBINANT FUSION PROTEINS THAT TARGET HOST

CELLS

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

# TRANSMITTAL LETTER

# Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement (6 pages), Form PTO-1449 (1 page), cited non-U.S. patent documents (1 bound volume) and a return postcard for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed after receipt of a first Office Action on the Merits in the above-referenced application, a check for the filing fee of \$180.00 is enclosed.

The Commissioner is hereby authorized to charge any fees that may be due in X connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully Jubmitted,

Stephante Seidman

Reg. No. 33,7亿タ

Attorney Docket No. 21865-002001/6502

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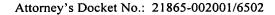
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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR \$1/10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Seidman





Title

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mang et al. Art Unit: 1652

Serial No.: 10/718,986 Examiner: Tekchand Saidha, Ph.D.

Filed: November 21, 2003 Conf. No.: 3664 Cust. No.: 20985

: ANTIVIRAL RECOMBINANT FUSION PROTEINS THAT TARGET HOST

CELLS

Mail Stop: Amendment Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, a check for the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (1 page) and copies of the cited non U.S. Patent documents (1 bound volume) are provided herewith.

08/02/2007 AAHMADI 00000044 10718986 01 FC:1806

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EV 471537527 US Date of Deposit July 31, 2007

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Stephanie Seidman

Applicant: Mang et al. Attorney's Docket No.: 21865-002001/6502

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The documents cited on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Provided herewith is a copy of an Office Action (Document I), issued May 22, 2007, in corresponding U.S. application, Serial No.10/939,262 (Attorney Docket No. 21865-002002/6502B). U.S. application, Serial No. 10/939,262 is a continuation-in-part of the instant application and claims priority to U.S. provisional applications Serial Nos. 60/464,217 and 60/428,535, to which the instant application also claims priority. The table below lists Document I and includes a column that provides a space next to the document to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document
	I	Copy of Office Action, issued May 22, 2007, in connection with corresponding U.S. Patent Application No. 10/939,262

Further, the Office's attention is directed to the following facts and issues, which may be pertinent to this application:

# Litigation with Perlan Therapeutics, Inc.

Applicant presently is in California State Court litigation and previously was in Federal Court litigation with Perlan Therapeutics, Inc. (hereinafter Perlan) (Superior Court of the State of California for the County of San Diego; Case No. GIC 871276, Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang M.D. Ph.D., an individual, and Mang Yu, Ph.D., an individual, and Does 1 through 10, inclusive; United States District Court, Southern District of California, Case No. 05cv1855 BEN (BLM), Perlan Therapeutics, Inc. vs. NexBio, Inc., Fang Fang and Mang Yu a California Corporation and Case No. 06-CV-1701 WQH (LSP), Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang, and Mang Yu).

In these litigations, Perlan is the Plaintiff, and the Applicant of the instant application (Fang Fang, M.D. Ph.D. and Mang Yu, Ph.D.), and their company, NexBio Inc., are Defendants. One of several allegations by the Plaintiff relates to inventorship in the instant application. Plaintiff alleged that Perlan employee, Dr. Catherine Charles, should be named as an inventor on the instant patent application and on related patents and applications.

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Additional claims also have been brought against the Defendants by Perlan. Several documents related to the litigations are discussed here and identified in the table below. Copies are provided herewith.

# First Federal Complaint (Document II)

In a first Federal Complaint, filed in the United States District Court for the Southern District of California, dated September 27, 2005 (provided herewith as Document II), one of the Plaintiff's several allegations relates to inventorship in the instant application. Perlan alleged that Defendants "[f]ailed to name Dr. Charles an inventor" on several patent applications, including the instant application (U.S. Application No. 10/718,896); U.S. Provisional Application Nos.: 60/428,535, 60/464,217, 60/561,749 and 60/580,084, to each of which the instant application claims priority; PCT application PCT/US2003/037158; and U.S. Patent Application No. 10/939,262; asserting that the Defendants "inappropriately identified themselves, either singly or jointly as the only named inventors." Plaintiff sought an Order, based on 35 U.S.C. § 116, to "correct inventorship and name Dr. Charles to pending patent applications and/or issued patents" related to these applications. Other claims also were made in the first Federal Complaint.

# District Court Order Granting Motion to Dismiss and Entering Judgment in Defendants' Favor (Documents III and IV)

In a Motion to Dismiss Plaintiff's Complaint, Defendants moved to dismiss the federal claims (including the claim related to correction of inventorship of the instant application) brought against them by Perlan, based on lack of subject matter jurisdiction, and to dismiss state court claims. Defendants' arguments with respect to the inventorship issue were based on the assertion that 35 U.S.C. § 116 does not provide for a private cause of action on a pending application.

A District Court Order granting the motion to dismiss (provided herewith as Document III) dated August 3, 2006 and Judgment (provided herewith as Document IV), dated August 4, 2006, dismissed all of Plaintiff's claims, including the claim seeking an Order to correct inventorship based upon 35 U.S.C. §116. In this Order granting the motion to dismiss, the District Court agreed with Defendants' argument that the claim seeking a correction of inventorship "should be dismissed because § 116 does not provide for a private cause of action on a pending application." The Court asserted that the "Federal Circuit has noted that prior to a patent being issued, only the Director of the Patent Office is given

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authority to add a co-inventor," citing *Eli Lilly & Co. v. Aradignm Corp.*, 376 F .3d 1352 (Fed. Cir. 2004). In summary, the Order dismissed all federal claims brought against the Defendants, including that seeking correction of inventorship in the instant application, and dismissed all remaining claims as being matter of state law.

### Additional Documents (Documents V-XI)

Copies of additional documents are provided, relating to subsequent Complaints and rulings in the litigations, none of which is based on the issue of inventorship that was dismissed by the Federal Court Order as noted above. A second Federal Complaint filed on August 22, 2006 by Perlan in the United States District Court (Southern District of California) (Document V); an Order dismissing the second Federal Complaint, dated January 23, 2007 (Document VII); a United States Court of Appeals for the Federal Circuit Order (Document VII) dismissing Plaintiff's Appeal of the Order and Judgment entered in the first Federal case, dated February 12, 2007; a Second Amended Complaint filed in the Superior Court of the State of California for the County of San Diego by Perlan, dated April 10, 2007 (Document VIII); and Defendants' answers to the Second Amended Complaint, dated May 15, 2007 (Documents IX, X, and XI) are provided. As noted above, neither the second Federal Complaint (now dismissed) nor the Second Amended Complaint includes claims seeking correction of inventorship.

# **Documents II-XI**

The table below lists the Documents described above (Documents II through XI) related to the aforementioned litigation, and includes a column that provides a space next to each document to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document	
	П	Copy of first Federal Complaint, filed in the United States District Court, Southern District of California, dated September 27, 2005; Case No. 05cv1855 BEN (BLM) Perlan Therapeutics, Inc. vs. NexBio, Inc., Fang Fang and Mang Yu a California Corporation.	
·	III	Copy of Order granting motion to dismiss and denying plaintiff's motion to exercise supplemental jurisdiction, United States District Court, Southern District of California, dated August 3, 2006; Case No. 05cv1855 BEN (BLM) Perlan Therapeutics, Inc. vs. NexBio, Inc., et al.	

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Examiner Initial	Document No.	Document
	IV	Copy of Judgment in a civil case, United States District Court; Southern District of California, dated August 4, 2006; Case No. 05cv1855 BEN (BLM) Perlan Therapeutics, Inc. vs. NexBio, Inc., et al.
	V	Copy of second Federal Complaint, filed in the United States District Court, Southern District of California, dated August 22, 2006; Case No. 06-CV-1701 WQH (LSP); Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang, and Mang Yu.
	VI	Copy of Order dismissing case without prejudice, United States District Court, Southern District of California, dated January 23, 2007; Case No. 06-CV- 1701 WQH (LSP); Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang, and Mang Yu.
:. · ·	VII	Copy of Order dismissing appeal, United States Court of Appeals for the Federal Circuit, dated February 12, 2007; Case No. 05-CV-1855 BEN (BLM); Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang, and Mang Yu.
	VIII	Copy of Second amended complaint for damages and other relief, filed in the Superior Court of the State of California for the County of San Diego, dated April 10, 2007; Case No. GIC 871276; Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang M.D. Ph.D., an individual, and Mang Yu, Ph.D., an individual, and Does 1 through 10, inclusive.
	IX	Copy of Defendant NexBio, Inc.'s answer to plaintiff's Second Amended Complaint, filed in the Superior Court of the State of California for the County of San Diego dated May 15, 2007; Case No. GIC 871276; Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang M.D. Ph.D., an individual, and Mang Yu, Ph.D., an individual, and Does 1 through 10, inclusive.
	X	Copy of Defendant Fang Fang, M.D., Ph.D.'s answer to plaintiff's Second Amended Complaint, filed in the Superior Court of the State of California for the County of San Diego, dated May 15, 2007; Case No. GIC 871276; Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang M.D. Ph.D., an individual, and Mang Yu, Ph.D., an individual, and Does 1 through 10, inclusive.

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Applicant: Mang et al. Serial No.: 10/718,986

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Examiner Initial	Document No.	Document	
	XI	Copy of Defendant Mang Yu, Ph.D.'s answer to plaintiff's Second Amended Complaint, filed in the Superior Court of the State of California for the County of San Diego, dated May 15, 2007; Case No. GIC 871276; Perlan Therapeutics, Inc. vs. NexBio, Inc., a California Corporation, Fang Fang M.D. Ph.D., an individual, and Mang Yu, Ph.D., an individual, and Does 1 through 10, inclusive.	

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and that they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie Seidman

Reg. No. 33,779

Attorney Docket No. 21865-002001/6502

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Sheet	1	of	1

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Substitute For (Modified)	JUL	3 1 2007 3 Paten	partment of Commerce t and Trademark Office	Attorney's Docket No 21865-002001/0		Application No 10/718,98	
List of P	atents an	nd Publications	for Applicant's tatement	Applicant			
(37 CFR §1.98	B(b))	_		Filing Date November 21, 2	2003	Group Art Uni 1652	t
	• •		U.S. Patent	Documents			
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	NONE					

	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner	Desig.	Document	Publication	Country or			Trans	slation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AB	NONE						

	Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner	Desig.				
Initial	ID	Document			
	AC	Air et al., "Red cells bound to influenza virus N9 neuraminidase are not released by the N9 neuraminidase activity," Virology, 211; 278-284, (1995).			
	AD	Bergelson, et al., "Role of gangliosides in reception of influenza virus," European Journal of Biochemistry, 128(2-3):467-474, (1982).			
	AE	Els et al., "Sialic acid is cleaved from glycoconjugates at the cell surface when influenza virus neuraminidases are expressed from recombinant vaccinia viruses," Virology, 170(1):346-351, (1989).			
	AF	Gottschalk, A., Chemistry of virus receptors, p51-61. In F.M. Burnet and W.M. Stanley (ed.), The Viruses; biochemical, biological and biophysical properties. Academic Press, Inc., New York, NY, (1959).			
	AG	Griffin et al., "Effects of hexose starvation and the role of sialic acid in influenza virus release," Virology, 125(2):324-334, (1983).			
•	AH	Stray et al., Influenza virus infection of desialylated cells," Glycobiology, 10(7):649-658, (2000).			

Examiner Signature		Date Considered
•	•	

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.